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RE: ***OPIOID GUIDELINES***

Dear Dr. Paice and Dr. Sitzman:

It is with reluctance that I submit this letter to you regarding the proposed opioid guidelines. I am a longstanding member of both AAPM and APS and have been on both boards in the past. As you know, the guidelines are the product of a joint committee sponsored by APS and AAPM to develop these guidelines. I have been a member of that guideline committee. Nonetheless, I feel compelled to separate myself from the committee and express my concerns to you. I would not take such an unconventional step were it not that I consider this issue of significant importance and a matter of public safety.

I should first acknowledge that the development of these guidelines has been guided by scholarly and ethical efforts. Dr. Roger Chou deserves enormous credit for his scholarly and skillful efforts on behalf of the guideline project. He has had to manage diverse opinions, strong personalities, and scheduling challenges. Nonetheless, I am compelled to reject the guidelines as they are currently structured because they are devoid of a critical feature that I believe is necessary to protect public safety: pretreatment guidelines or expressed and delineated expectations regarding physician competence.

In order to assure the appropriate availability of opioids to those in need and at the same time protect the public from the well recognized risks that arise from improper and unwise administration or the failure to monitor use and safety, it is necessary that guidelines address:

a. Physician competence to evaluate chronic pain and determine the appropriate treatment and physician knowledge to prescribe opioids safely;
b. The importance of effective and responsible monitoring of usage and treatment efficacy, making certain that the treatment goals are achieved;
d. Physician willingness to discontinue opioids when appropriate.

In short, a well founded concept of risk management must be integrated into the guidelines.

It is my personal view that these guidelines are inadequate because of the absence of sufficient pretreatment competence expectations (item a).

With some minor exception, the guidelines ***assume*** that prescribing physicians will be sufficiently competent and knowledgeable so that they can effectively evaluate chronic pain patients to responsibly determine treatment needs. The guidelines in their current form principally focus on and emphasize the post-prescribing period and not the pretreatment period. *By failing to establish pretreatment competence expectations, the guidelines either assume competence or reflect the view that no special knowledge or experience is required to effectively and safely carry out the assessment and treatment of chronic pain patients.* I believe that most reasonable authorities would find that indefensible. In any case, it is a cause of serious concern for me and others. The U.S. has a serious prescription drug abuse problem. In many instances there appears to be a direct linkage between easy to excessive availability, ineffective assessment, unsafe prescribing patterns, and/or ineffective monitoring. (The guidelines do address monitoring, but not the pretreatment willingness or capability of physicians to undertake monitoring.)

Despite my efforts during the development process to influence these guidelines through the committee structure, my efforts were rejected.

The liberalization of opioid use for chronic non-cancer pain has brought both good and bad. There are many patients today who are living lives that have been salvaged and made more comfortable, if not productive and joyful, because of the availability and proper administration of opioids for what several years ago would have been considered a prohibited use. But it must also be acknowledged that liberalization has brought considerable harm also, and it is to this point that my strong feelings are directed.

I should note that in the introduction of these guidelines, "headache" is mentioned. I am not certain that this is appropriate, since I believe most headache specialists in this country are not, except rarely, in favor of chronic opioid therapy for chronic headache patients, and many have opinions much stronger than mine. Accumulating scientific data support the likelihood that opioids activate the very mechanisms that promote headache and illness progression and refractoriness to treatment. I and many of my colleagues, such as Dr. Fred Sheftell, current president of the American Headache Society, have been writing about this for years.

Perhaps it would be of some interest to you that at a recent meeting of the American Academy of Neurology, I was asked to formally debate a prominent expert in general pain on whether opioids are "correctly prescribed and appropriately managed in headache patients." My position was, of course, in the negative - that opioids are not correctly prescribed or appropriately administered.

TO: DRS. PAICE AND SITZMAN
FROM: DR. JOEL SAPER
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The audience gave my presentation unanimous support. There was not one vote in favor of the affirmative position.

Finally, I must point out another important concern. It is reasonable to assume that the guideline project has either directly or indirectly been supported by the opioid industry. The sponsoring organizations have received a large amount of funding from the opioid manufacturers over the past decade. Many members of the committee have personally received sizable funding from the opioid industry as well. Congress currently is intently interested in both the prescription drug problem and how physicians and professional organizations are influenced by the flow of dollars to them from the pharmaceutical industry, and how this influences treatment policy, guideline development, and teaching.

If nothing else, this should compel a serious consideration of these guidelines in the perspective of our responsibility to establish with ***absolute certainty*** that these guidelines advance the protection and safety of the public (as well as our colleagues) and place the very highest priority ***on doing no harm***. I believe that these guidelines have not achieved that.

The zeal to aggressively treat pain may have placed our responsibility to "first do no harm" in second position. *In my view the guidelines have set the bar so low for initial administration by any physician who has a medical license and DEA number that the guidelines will in fact encourage use by those who are unprepared to carry out the task responsibly and safely.*

Such guidelines, developed with the support of industry and by many who have been personally paid large sums by industry, create a nexus that will not be ignored.

In short, the absence of pretreatment competence expectations from this scholarly group of physicians and other professionals suggests that nothing special is necessary. I believe this is a dangerous position, given the current circumstances. We should know better. *Chronic pain does not compel an emergency response, as might be argued by the case of acute pain.* Diligent training and competence should be prerequisites to the chronic administration of opioid therapy. These guidelines do not advance this principle.

Deaths and harms have come to many patients prescribed opioids. The media knows it. Government and regulatory agencies know it. Our guidelines must do a better job of addressing it!

Sincerely,

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JRS:daj 5/15

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